

REMARKS

The specification has been amended to include the required SEQ ID NO: identifiers in the brief description of FIG. 4 as requested by the Examiner.

Claims 1-9, 12-13, and 19-34 have been amended. The amendments do not constitute new matter and are fully supported by the original claims, the sequence listing, and the specification. Specifically, support for the above amendments can be found in the specification on p. 1, paragraph [0001], p. 3, paragraph [0009], and p. 4, paragraph [0010] (supporting the additional limitation of administering the test compound to a mammal in a separate in vivo assay measuring the effect of the test compound on the body weight of the mammal); pp. 16-17, paragraph [0042] (supporting the limitation of contacting a test compound with a protein or nucleic acid molecule encoding a protein having an amino acid sequence at least about 85%, 95%, 96%, 97%, 98%, or 99% identical to the amino acid sequence of mammalian sequence #115 - SEQ ID NO: 6); pp. 4-7, paragraphs [0010], [0011], [0013], [0016], [0017], p. 12, paragraph [0030], and p. 29, paragraph [0070] (supporting the limitation of a protein fragment of mammalian sequence #115 - SEQ ID NO: 6- having at least 8 amino acids). Claims 2, 4, 6-13, 15-18, 20-24, 26, 27, 29, 31, 32 and 34-36 have been withdrawn by the Examiner as non-elected. Thus, claims 1, 3, 5, 14, 19, 25, 28, 30, 33, and 35-36 are pending.

The Applicants expressly rebut any presumption that the Applicants have surrendered any equivalents under the doctrine of equivalents and expressly state that the claims, as amended, are intended to include and encompass the full scope of any equivalents as if the claims had been originally filed and not amended. If the Examiner disagrees or does not examine the claims (including considering any prior art) with the understanding that the amended claims include and encompass the full scope of all equivalents under the doctrine of equivalents as if the claims had been originally filed, the Applicants respectfully request that the Examiner note this on the record in writing. Otherwise, the Examiner agrees that any such presumption has been rebutted by the

understanding that such claims include and encompass the full scope of all equivalents under the doctrine of equivalents as if the claims had been originally filed and not amended.

I. Restriction Requirement

The Examiner notes that she has considered the Applicants arguments in response to the restriction requirement but nonetheless deems the restriction requirement proper. As a consequence, the Examiner has made the restriction requirement final withdrawing claims 2, 4, 6-13, 15-18, 20-24, 26, 27, 29, 31, 32, and 34-36 as nonelected inventions. The Applicants continue to respectfully disagree with the Examiner's restriction requirement and plan to petition the Director under 37 C.F.R. § 1.144 under separate cover for the rejoinder of Groups I-XIV.

II. Sequence Compliance

The Examiner states that the application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because there are sequences in FIG. 4 that do not contain a SEQ ID NO. In response, the specification has been amended to include the required SEQ ID NO: identifiers in the brief description of FIG. 4 as requested by the Examiner.

III. Claim Rejections Under 35 USC § 112, Indefiniteness

Claims 1, 3, 5, 14, 19, 25, 28, 30 and 33 are rejected under 35 U.S.C. § 112, first paragraph, for indefiniteness. The Examiner states that it is unclear what "mammalian sequence #115" means (i.e., polypeptide or polynucleotide). In response, the Applicants have clarified the claims by the above amendments and replaced the term "mammalian sequence #115" with SEQ. ID NO: 6. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

IV. Claim Rejections Under 35 USC § 112, Written Description

Claims 1, 3, 5, 14, 19, 25, 28, 30 and 33 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that due to the lack of clarity with respect to the term "mammalian sequence #115," the skilled artisan would not be able to recognize that the applicant was in possession of the claimed invention at the time of filing. In response, the Applicants have amended the claims to address the Examiner's concerns and replaced the term "mammalian sequence #115" with SEQ. ID NO: 6. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

V. Claim Rejections Under 35 USC § 112, Enablement

Claims 1, 3, 5, 14, 19, 25, 28, 30 and 33 are rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner asserts that the specification does not reasonably provide enablement for a method of making and using the claimed invention. According to the Examiner, the specification does not teach a link between a compound's ability to bind mammalian sequence #115 and the modulation of body weight, nor has any teaching in the prior art been located that describes such a link. The Examiner further asserts that "due to the lack of guidance in the specification as filed, as well as in the prior art, regarding how identifying a test compound that binds to mammalian sequence #115 would impact modulation of body weight, there is no perceived correlation between binding mammalian sequence #115 and modulation of body weight."

In response, the Applicants note that the claims have been amended to include the additional limitation of performing an in vivo assay to test the effect of the compound on body weight. Accordingly, the invention is not directed to methods of identifying compounds that bind to mammalian sequence #115 as compounds that necessarily modulate body weight per se; but rather, the invention is directed to methods of

identifying (or pre-selecting) compounds that bind to mammalian sequence #115 as compounds to further screen or test in separate in vivo assays to determine their effect on body weight.

One of the utilities of the claimed invention is that it narrows down the number of compounds to screen or test with regard to body weight modulating activity. Part of the novelty and unobviousness of the present invention lies in the discovery that the expression level of the G-protein coupled receptor- mammalian sequence #115 (as exemplified by the SEQ ID NOS of the present invention)- is altered by changes in body weight. Therefore, compounds that bind to mammalian sequence #115 (as exemplified by the SEQ ID NOS of the present invention) by their very nature (in light of the novel discovery of the present invention) become primary candidates or leads to test in separate in vivo assays to determine whether they modulate body weight. Thus, the claimed invention is, in essence, directed to novel research methods of screening compounds that modulate body weight.

Contrary to the Examiner's assertion, there is a reasonable correlation between body weight and the expression of mammalian sequence #115 (as exemplified by the SEQ ID NOS of the present invention). For instance, Example 4 and Figure 3 show that the expression of murine sequence #115 (sequenced and identified in Figure 4 as "MOUSEGN_CHR7-36867") was altered in diet induced obese mice. In fact, several alterations occurred. Specifically, a 1.6 fold decrease occurred in the expression of mRNA of this gene in obese mice vs. control mice in the arcuate nucleus region of the brain and ventromedial hypothalamus region of the brain; and more significantly, a 5 fold decrease occurred in the expression of mRNA in obese mice vs. control mice in the posterior pituitary region of the brain. Expression levels were also altered in other areas of the brain in obese mice vs. control mice as shown in Figure 3.

Thus, the claims (as amended) are fully enabled by the specification. Accordingly, the Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement be withdrawn.

VI. Claim Rejections Under 35 USC § 102(b), Glucksmann

Claims 1, 3, 5, 14, 19, 25, 28, 30 and 33 are rejected under 35 U.S.C. § 102(b) as anticipated by Glucksmann et al (WO 99/37679). The Examiner asserts that Glucksmann teaches methods of identifying compounds that bind and modulate the expression of a G-protein coupled receptor (flh2882). According to the Examiner, the flh2882 DNA sequence is 1728 nucleotides long and is 99.7% identical with SEQ ID NO: 5 where it overlaps with SEQ ID NO: 5.

In response, the Applicants note that Glucksmann does not disclose all the elements of the claims as amended. In order for a reference to anticipate a claim under 35 U.S.C. § 102, the reference must disclose every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference." See MPEP § 2131.

Glucksmann fails to disclose any correlation or relationship of the flh2882 gene or protein with the modulation of body weight. All the rejected claims of the present invention have been amended to include the additional limitation of performing an in vivo assay to test the effect of the compound on body weight. This limitation is not disclosed or suggested by Glucksmann (either expressly or inherently).

Accordingly, because Glucksmann fails to disclose all the elements of each claim expressly or inherently, the rejection under 35 U.S.C. § 102 should be withdrawn.

VII. Claim Rejections Under 35 USC § 102(a) & 102(e), Liaw

Claims 1, 3, 5, 14, 19, 25, 28, 30 and 33 are rejected under 35 U.S.C. § 102(a) or 102(e) as anticipated by Liaw et al (WO 02/068600). The Examiner asserts that Liaw teaches methods of identifying compounds that bind and modulate the expression of a G-protein coupled receptor. According to the Examiner, Liaw teaches a DNA sequence that is 1014 nucleotides long and is 98.3% identical to SEQ ID NO: 5.

In response, the Applicants note that Liaw does not disclose all the elements of the claims as amended. In order for a reference to anticipate a claim under 35 U.S.C. § 102, the reference must disclose every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference." See MPEP § 2131.

Liaw fails to disclose any correlation or relationship of Liaw's G-protein coupled receptor with the modulation of body weight. All the rejected claims of the present invention have been amended to include the additional limitation of performing an in vivo assay to test the effect of the compound on body weight. This limitation is not disclosed or suggested by Liaw (either expressly or inherently).

Accordingly, because Liaw fails to disclose all the elements of each claim expressly or inherently, the rejection under 35 U.S.C. § 102 should be withdrawn.

VIII. Conclusion

Entry of the foregoing remarks and amendments is respectfully requested. No fee is believed to be due in connection with the filing of this Amendment, other than the fee for the Petition For Extension of Time. However, if any other fee is deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account No. 08-2525.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Brian Remy", is written over a horizontal line.

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